

Kit Configuration

P/N 3000-2181	2 x 14 mL TOXO R1 2 x 3.5 mL TOXO R2
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Reagent Preparation

P/N 3000-2181 TOXO R1: Ready to use.
TOXO R2: Ready to use. Invert to mix well before first use.
Place the bottles into reagent tray.

In Use Stability

For optimal stability remove reagents from the system after use, and store them at 2-8°C in the original vial securely closed.

Specimen

Serum.

Calibration

Use *quantex* TOXO standard Cat. No 300-2184. The calibrator concentration is indicated on the vial label. Instrument will perform auto dilution of standard (SS). Recalibrate every 28 days or when a new lot of reagent is used.

Quality Control

Use *quantex* TOXO Control Cat. No.3000-2185.

Calculation of Analytical Results

The results concentration is automatically calculated by the instrument against the Calibration curve. For detailed description, refer to the Instrument settings and to the ILab 350 Operator Manual.

Interpretation of results

Result	Interpretation
< 6 IU/mL	Negative
6-10 IU/mL	Doubtful
> 10 IU/mL	Positive

Concentrations of toxoplasma antibodies:

- Under 6 IU/mL: Should be interpreted as absence of toxoplasma antibodies. If the serum tested corresponds to a pregnant woman, it is advisable to repeat the test during the pregnancy period (once every month) to detect a possible seroconversion.
- Between 6 and 10 IU/mL: Should be interpreted as presence of toxoplasma antibodies at very weak level.
- Over 10 IU/mL: Should be interpreted as presence of toxoplasma antibodies which may reflect either a past infection or an acute infection. In this case it is recommended to investigate the presence of specific IgM toxoplasma antibodies.

Reference Interval

See Package insert enclosed in the kit.

References / Literatur / Bibliografia / Bibliographie / Bibliografía /

See package insert enclosed in the kit

Performance Characteristics

Limitation/Interfering Substances

No interference has been observed in hemolyzed or icteric serum. Very lipemic or turbid samples should be clarified by high speed centrifugation before running the assay. To study possible interferences, samples with potential risk of producing cross reaction were tested, including sera positive for rheumatoid factor (RF), anti-nuclear antibodies (ANA) and from pregnant women. No evidences of interference were observed. For a comprehensive review of interfering substances, refer to the publication by Young, *et al.*¹

Precision

	Samples/Runs	Mean (IU/mL)	CV(%)
Within run	4/10	44	1.5
Total	4/10	44	7.6

Method Comparison

The *quantex* TOXO was studied in comparison to (MEIA) using a serum panel of 51 positive samples for IgG antibody, 15 positive samples for IgG and IgM antibodies, and 46 negative samples. The relative sensitivity was 100%, the relative specificity was 97.7%, the positive predictive value was 98.6% and the negative predictive value was 100%.

Linearity

no rerun 5- 100 IU/mL ; with rerun 5- 800 IU/mL

Minimum Detection Limit

5 IU/mL

Quantification Limit

5 IU/mL

Instrument Settings

Chemistry Parameters		R1	
Method Name	<input type="text" value="TOXO"/>	Reagent Name	<input type="text" value="TOXO"/> Volume <input type="text" value="140 μL"/>
Unit	<input type="text" value="IU/mL"/>	R2	<input type="text" value="enable"/>
Assay Type	<input type="text" value="End"/>	Reagent Name	<input type="text" value="TOXO"/> Volume <input type="text" value="60 μL"/>
Measuring Points	1 enable start <input type="text" value="14"/> end <input type="text" value="15"/>	Wash	disable Reagent Name <input type="text"/>
	2 enable start <input type="text" value="25"/> end <input type="text" value="26"/>	Diluent	enable Reagent Type <input type="text"/>
Wave Length		Diluent	enable Reagent Name <input type="text" value="Saline"/>
Prim	<input type="text" value="570"/> Sec <input type="text"/>	Decimal Points	<input type="text" value="1"/>
Sampling Volume	<input type="text" value="15 μL"/>	Normal Range	<input type="text" value="0"/> <input type="text" value="10"/>
Dilution	disable	Technical Range (Conc)	<input type="text" value="0.0"/> <input type="text" value="100"/>
Rerun (High)	<input type="text" value="15 μL"/>	mAbs/10	<input type="text" value="-30000 / 30000"/>
Dilution	enable	RPT Wash (R1)	<input type="text" value="Sys Water"/>
Rerun (Low)	<input type="text" value="30 μL"/>	(R2)	<input type="text" value="Sys Water"/>
	<input type="text" value="15"/> <input type="text" value="20"/> <input type="text" value="140 μL"/>	Instrument Factor a	<input type="text" value="1"/> b <input type="text" value="0"/>
	<input type="text" value="30 μL"/>	Stirring Speed	R1 <input type="text" value="high"/> R2 <input type="text" value="high"/>

Calibration Checks

** Duplicate Limit	<input type="text"/>	** mAbs/10	Sampling Method for Standards
** Sensitivity Limit	<input type="text"/>	** mAbs/10	<input checked="" type="checkbox"/> Duplicate
** Linearity Limit	<input type="text"/>	%	<input type="checkbox"/> Triplicate
** Prozone Limit	<input type="text"/>	upper	Blank measurement
SL1-S	<input type="text"/>	SL1-F	<input checked="" type="checkbox"/> Enable Reagent blank
SL2-S	<input type="text"/>	SL2-F	<input type="text" value="None"/>
Sens	<input type="text"/>	mAbs/10	Reagent blank measurement at calibration
<input checked="" type="checkbox"/> Absorbance Limit	<input type="text"/>		<input checked="" type="checkbox"/> Reagent blank (system water)
Reaction	<input type="text" value="Increase"/>		Multiplex measurement is the same as standards
Limit	<input type="text" value="25000"/> mAbs/10		Reagent Blank Limit Checks
			<input type="text"/>
			** Duplicate limit <input type="text" value="50"/> mAbs/10

Calibration

Method	<input type="text"/>	Name	<input type="text" value="TOXO"/>	Interval	<input type="text" value="28"/> days
Calculation	<input type="text" value="Point to Point"/>				
	Conc	WORK	MASTER	Lot No	
S1	<input type="text" value="0"/>	<input type="text" value="-35"/>			K <input type="text" value="N/A"/>
S2	<input type="text" value="6.25"/>	<input type="text" value="133"/>			
S3	<input type="text" value="12.5"/>	<input type="text" value="268"/>			
S4	<input type="text" value="25"/>	<input type="text" value="652"/>			
S5	<input type="text" value="43.8"/>	<input type="text" value="1396"/>			
S6	<input type="text" value="100"/>	<input type="text" value="4042"/>			

Calibration (2/2) Autodilution

Serial Dilution	<input checked="" type="checkbox"/> enable	<input type="checkbox"/> disable	Claculation	<input type="text" value="Point to Point"/>
	Conc	Post Sampling (μL)	Pre Sampling (μL)	Diluent(μL)
S1	<input type="text" value="0"/>	<input type="text" value="15"/>	<input type="text" value="0"/>	<input type="text" value="80"/>
S2	<input type="text" value="6.25"/>	<input type="text" value="15"/>	<input type="text" value="5"/>	<input type="text" value="75"/>
S3	<input type="text" value="12.5"/>	<input type="text" value="15"/>	<input type="text" value="10"/>	<input type="text" value="70"/>
S4	<input type="text" value="25"/>	<input type="text" value="15"/>	<input type="text" value="20"/>	<input type="text" value="60"/>
S5	<input type="text" value="43.8"/>	<input type="text" value="15"/>	<input type="text" value="35"/>	<input type="text" value="45"/>
S6	<input type="text" value="100"/>	<input type="text" value="15"/>	<input type="text" value="0"/>	<input type="text" value="0"/>

Reagent Registration

Reagent Code	<input type="text" value="0163"/>								
Reagent Name	<input type="text" value="TOXO"/>								
R1	<input checked="" type="checkbox"/> enable	Volume (L)	<input type="text" value="**"/> mL	Volume (S)	<input type="text" value="**"/> mL	Stability Check	<input checked="" type="checkbox"/> enable	Term	<input type="text" value="**"/> days
R2	<input checked="" type="checkbox"/> enable	Volume (L)	<input type="text" value="**"/> mL	Volume (S)	<input type="text" value="**"/> mL	Stability Check	<input checked="" type="checkbox"/> enable	Term	<input type="text" value="**"/> days

** Operator definable N/A not applicable to this test Calibration curve is only as example

